

REMARKS

Claim 78 has been amended. Claims 58-70, 75-88 and 93-95 remain in the application.

Claim 78 was rejected under 35 U.S.C. 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular the limitation "the cutout" in which there was insufficient antecedent basis.

Claim 78 has been amended to correctly cite "the opening", which has antecedent basis in claim 75. The Applicant respectfully requests withdrawal of this rejection.

Claims 58, 59, 61, 63 and 69 were rejected under 35 U.S.C. 102(e) as being anticipated by Augustine '482. That rejection is respectfully traversed for the following reasons.

Axiomatically, rejection of a claim for anticipation by a reference requires that the reference include all steps or elements, and all limitations positively recited in the rejected claim. If the reference omits any subject matter explicitly recited in the claim, and the missing subject matter is considered to be inherent, extrinsic evidence must be introduced to show that the missing omitted subject matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.

The rejected claims recite a combination that includes "a surgical drape attached to, or formed integrally with," an inflatable portion. A "surgical drape" has a particular construction, form and function that are known in the art. In this regard, see the attached article from the Mahidal University SPECTRUM entitled "Ramathiboti Hospital Develops Simplified Surgical Drapes for Performing Caesarian Sections on HIV-Infected Mothers". A surgical drape is defined and explained in the second full paragraph of that article. Element 70 in Augustine '482 is a "foot drape". The foot drape 70 functions to trap and retain warmed air around a patient's feet. See Augustine at Col. 7, lines 54-62. This element is nowhere described or referred to as a "surgical drape". Accordingly, Augustine '482 omits a "surgical drape". If a surgical drape is considered to be inherent in Augustine '482, the applicant requests the introduction of extrinsic evidence in this regard. Otherwise, the applicant respectfully requests withdrawal of this rejection.

Claims 60, 62, 64-67, 70, 75-85, 87, 88 and 93-95 were rejected under 35 U.S.C. 103(a) as being unpatentable over Augustine '482 further in view of Irani. That rejection is respectfully traversed for the following reasons.

The Office Action states that "Augustine et al. teach all of the limitations of the claims except an opening and the inflatable portion being configured to cover the upper and lower extremities. Irani discloses a similar blanket where the inflatable portion is configured to cover

the upper and lower extremities and teaches that it is old and well known in the art to provide an opening in the blanket to provide access through the blanket to perform a surgical procedure."

An invention is unpatentable only if the differences between it and the prior art would have been obvious at the time of the invention. *Prima facie*, rejection of a claim for obviousness over a combination of references requires some suggestion or motivation, either in the references, or in the knowledge generally available to one of ordinary skill in the art, to combine the references, a reasonable expectation of success, and the inclusion, explicitly or by suggestion, of all elements or steps, and all limitations of the rejected claim.

Augustine '482 describes an inflatable device with a "foot drape" which "traps and retains heat around the patient's feet to warm the feet". (Augustine, col. 7, lines 56-57). Irani describes an inflatable air blanket with an aperture in a central portion of the blanket (Irani, col. 7, lines 16-18).

Although each of the references relates to an inflatable device, there is no suggestion to modify Augustine's inflatable device in such a way as to provide a surgical drape or a surgical drape "attached to, or formed integrally with," an inflatable portion. Irani teaches an inflatable thermal blanket, but one without a "surgical drape". The claimed invention is a combination comprehending an inflatable portion and "a surgical drape". Neither prior art reference describes a surgical drape or any corresponding element which can be combined with an inflatable portion to provide a barrier between a surgical site and other parts of a body.

In fact, Irani teaches away from incorporation of a surgical drape into an inflatable device, stating: "it can be seen that the blanket 210 eliminates the need to provide a separate warming blanket and draping material for a surgical operation..." (Irani, col. 7, line 27-31). Since Irani specifically and explicitly excludes "draping material for a surgical operation" from the ambit of an inflatable device, the proposed combination is not suggested.

No evidence has been presented in the Official Action that the modification of the cited prior art references provides a reasonable expectation of success.

The combination also fails to satisfy the third requirement. Neither Augustine nor Irani includes a surgical drape. As pointed out above, Augustine teaches only a foot drape for trapping warmed air, while Irani teaches away from the use of a surgical drape. The combination, therefore, does not teach all the elements set forth in claims 58 and 75. Claims 60, 62, 64-67 and 70, dependent from claim 58 and claims 76-85, 87, 88 and 93-95, dependent from claim 75, also benefit from the above-mentioned distinctions between the proposed combination and the claimed invention. Accordingly, the applicant respectfully requests that the rejection be withdrawn.

Claims 68 and 86 were rejected under 35 U.S.C. 103(a) as being unpatentable over Augustine et al. and Irani further in view of Collins. That rejection is respectfully traversed for the reasons given above for claim 75 and amended claim 58. Claim 68 depends from amended claim 58 and claim 86 depends from claim 75, both of which have been shown above to be patentably distinguishable over Augustine/Irani. Collins does not rectify the deficiencies of that combination, and the applicant respectfully requests withdrawal of this rejection.

Claims 59-70, 75-88 and 93-95 were rejected under the judicially created doctrine of double patenting over claims 1-49 of U.S. Patent No. 5,941,907. A Terminal Disclaimer is submitted with this response and withdrawal of this rejection is respectfully requested.

A check for \$55 accompanies this paper for the Terminal Disclaimer fee. The Commissioner is hereby authorized to charge any additional fees, or credit any overpayment, that may be associated with this communication to Deposit Account No. 50/2258. A duplicate copy of this sheet is enclosed.

Respectfully submitted

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

78. (Amended) A surgical barrier device in accordance with claim 77, wherein the inflatable device has a recess at an end thereof, and the [cutout] opening is adjacent to the recess.



Ramathibodi Hospital Develops Simplified Surgical Drapes for Performing Caesarean Sections on HIV-Infected Mothers

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Surgeons and assistants are at risk of being infected while performing surgical procedures on HIV-positive patients, due to exposure to bodily fluids which can carry the virus. This is very true in the case of performing Caesarean sections (C-sections) -- delivery of a baby by cutting through the abdominal and uterine walls -- which involves exposure to both maternal blood and amniotic fluid. Equally important, it is also necessary to protect the newborn from possible infection.

Normally, a '**surgical drape**', or sterile covering, is used to form an aseptic field to prevent transportation of microorganisms. In the past, when few infectious diseases that could occur during pregnancy were known, reusable abdominal drapes and gowns were routinely used. However, the laundering of these possibly-contaminated materials is problematic, and eventually reduces their barrier qualities. Synthetic disposable drapes and gowns prove more effective in today's environment.

A problem, however, is that imported disposable drapes are more expensive, an important factor in developing countries when resources are limited. Furthermore, in the past no special vulvar drape existed for the prevention of surgical soiling during the operation. Doctors from MU's Ramathibodi Hospital have recently alleviated these problems by developing simplified disposable abdominal and vulvar drapes. The team responsible -- consisting of Dr. Winit Phuapradit, Professor and Chairman, and Dr. Panyu Panburana, Asst. Prof., both of the Dept. of Obstetrics and Gynaecology, along with Assoc. Prof. Weena Bullungpoti, Dept. of Nursing -- recently wrote of their invention in an article published in the International Journal of Gynaecology & Obstetrics.

Their efforts stem from encountering these obstacles while undertaking the '**Ramathibodi Elective Delivery Project**', implemented in October 1998 in response to the well-established fact that scheduled or elective C-section reduces the likelihood of accidental HIV-transmission, compared to vaginal delivery or unscheduled C-section. Elective C-section, performed before the onset of labor and consequent rupture of membranes, prevents transplacental maternal-fetal microtransfusion of blood and HIV during uterine contractions. Moreover, the infant is not exposed to infected cervicovaginal secretions and blood. C-section is thus widely recommended for HIV-infected mothers.

The Ramathibodi team made the simplified disposable abdominal

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drape from an ordinary polyethylene plastic bag, a transparent polyurethane acrylate glued sticker with paper backing, and two pieces of water-repellent, non-woven cloth. During the surgery, a square aperture is made in the center of one surface of the plastic bag, with the edge of the aperture elevated by flexible plastic bars. The sticker is mounted on the bag's other surface, adhering to the patient's abdomen after removal of the paper backing. The water-repellent cloths are attached to the upper and lower ends of the bag and all edges are sealed to prevent fluid leakage, forming a large rectangular '**collection pouch**' that covers the operative area to collect potentially contaminated fluids and thus prevent surgical soiling. The surgeon makes the incision through the plastic drape and the fetus is eventually delivered within the pouch.

The vulvar drape is made of an ordinary polyethylene plastic bag with its anterior surface cut off in a V-shape and two ovoid-shaped apertures made along the borders of the V-shaped edges. The upper plastic edges of these two apertures are cut in the middle, making the aperture size adjustable for strapping around the patient's upper thighs. A fluid back-flow-preventing mattress is placed along the posterior surface of the upper border of the bag. Contaminated fluids and blood from the vaginal canal are then collected within the pouch of this vulvar drape.

Senior obstetric staff at Ramathibodi Hospital employed these techniques in performing elective C-sections on 17 HIV-infected patients from March to September 1999. A study revealed that the procedures were well-tolerated by all patients, and that both drapes effectively prevented surgical soiling.

Both drapes are assembled and sterilized by ethylene oxide gas, available at the hospital, at a cost of only US\$ 5. These hospital-made simplified disposable drapes thus provide efficient collection and disposal of amniotic fluid and blood via abdominal incision and vaginal canal, thereby reducing the risk to the surgeons. This technique offers a safe and inexpensive draping method for elective C-section in cases of maternal HIV-infection. Moreover, it facilitates the role of elective C-section in cost-benefit terms for the reduction of perinatal HIV-transmission, especially in developing countries.

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